

MAY 25 2005

Page 1 of 5

K051092

**Premarket Notification 510(k) Summary**  
**As required by section 807.92**  
**Datex-Ohmeda S/5™ Compact Airway Module (model family E-CAiOVX) E-CAiOVX, E-CAiOV, E-CAiO, E-COVX, E-COV, E-CO and accessories.**

**GENERAL COMPANY INFORMATION as required by 807.92(a)(1)**

**COMPANY NAME/ADDRESS/PHONE/FAX:**

GE Healthcare  
86 Pilgrim Road  
Needham, MA 02492 USA  
Tel: 781-449-8685  
Fax: 781-433-1344

**NAME OF CONTACT:**

Mr. Joel Kent

**DATE:**

April 19, 2005

**DEVICE NAME as required by 807.92(a)(2)**

**TRADE NAME:**

Datex-Ohmeda S/5™ Compact Airway Module (model family E-CAiOVX) E-CAiOVX, E-CAiOV, E-CAiO, E-COVX, E-COV, E-CO and accessories.

**COMMON NAME:**

Airway gas, pressure and volume, anesthetic agent and agent identification and gas exchange monitor. Airway gas and Patient Spirometry accessories.

CLASSIFICATION NAME:

The following Class II classifications appear applicable:

<u>Product Code</u>	<u>Classification Name</u>	<u>CFR Section</u>
CCK	Analyzer, Gas, Carbon-Dioxide, Gaseous-phase	868.1400
CCL	Analyzer, Gas, Oxygen, Gaseous-phase	868.1720
BZK	Spirometer, Monitoring (W/WO alarm)	868.1850
CAP	Monitor, Airway Pressure (Includes gauge and/or alarm)	868.2600
CBR	Analyzer, Gas, Nitrous-Oxide, Gaseous-phase (Anesthetic co)	868.1700
BZL	Computer, Oxygen-uptake	868.1730
CBQ	Analyzer, Gas, Enflurane, Gaseous-phase (Anesthetic conc.)	868.1500
CBS	Analyzer, Gas, Halothane Gaseous-phase (Anesthetic conc.)	868.1500
NHO	Analyzer, Gas, Desflurane, Gaseous-phase (Anesthetic conc.)	868.1500
NHQ	Analyzer, Gas, Isoflurane Gaseous-phase (Anesthetic conc.)	868.1500
NHP	Analyzer, Gas, Sevoflurane, Gaseous-phase (Anesthetic conc)	868.1500

NAME OF LEGALLY MARKETING DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda S/5™ Compact Airway Module family, E-CAiOVX is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M-CAiOVX Module (K001814).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The Datex-Ohmeda S/5™ Compact Airway Module, E-CAiOVX is a double-width plug-in parameter module for monitoring respiratory (CO<sub>2</sub>, O<sub>2</sub>, N<sub>2</sub>O, anesthetic agents, anesthetic agent identification and respiration rate), ventilatory (airway pressure, volume and flow) and gas exchange parameters (Oxygen Consumption VO<sub>2</sub>, Carbon Dioxide production VCO<sub>2</sub>, Respiratory Quotient RQ, and Energy Expenditure, EE). The E-CAiOVX is a Compact Airway measuring module for a modular monitoring system.

The intended use for the modified device is the same as for the predicate, Datex-Ohmeda M-CAiOVX module (K001814) The indications for use are also the same.

There has been no change to the basic technology from the predicate. The E-CAiOVX module is a facelifted version of the predicate M-CAiOVX module. The module cover and mechanics have changed, but the fundamental scientific technology is the same as in the predicate device M-CAiOVX (K001814). The electronic measurement boards are the same in E-CAiOVX and M-CAiOVX, except for one component type change (EEPROM), and the software is basically the same, although both the software code and revision has changed during the five years since the predicate submission. Software changes include mostly improvements simplifying manufacturing and tests during manufacturing. There are also some enhancements in the mechanics of the E-CAiOVX module compared with the predicate M-CAiOVX, e.g. EMC cover is better implemented into the mechanics. The EMC specifications for the E-CAiOVX and M-CAiOVX modules are the same. The Datex-Ohmeda Compact Airway Module module, E-CAiOVX can be used with the following Datex-Ohmeda modular monitors with any monitor software (\*)

- S/5™ Anesthesia Monitor (AM) with monitor software S-STD93 or newer (\*)
  - S/5™ Compact Anesthesia Monitor (CAM) with monitor software S-STD93 or newer (\*)
  - S/5™ Critical Care Monitor (CCM) with monitor software S-ICU97 or newer (\*)
  - S/5™ Compact Critical Care Monitor (CCCM).with monitor software S ICU97 or newer (\*)
- (\*) The Gas exchange measurement works only with software versions 99 or newer. All monitors can be upgraded to software version 99 by using the U-LIFE U-xxx99(A).

The E-CAiOVX module consists of:

- TPX infrared measuring sensor for measuring CO<sub>2</sub>, N<sub>2</sub>O and anaesthetic agents
- Paramagnetic O<sub>2</sub> sensor
- Side-Stream Spirometry measurement
- Gas Exchange measurement

The E-CAiOVX's TPX infrared sensor is also capable of measuring anesthetic agents (Enflurane, Halothane, Sevoflurane, Isoflurane and Desflurane).

The E-CAiOVX module uses the same measurement technology and accessories as the predicate device, M- CAiOVX (K001814). The main accessories include airway gas sampling lines, D-fend water traps, Spirometry measurement tubing and D-lite sensors. The sampling line and the spirometry tube are attached to the module connectors. The monitor is switched on and the gas sampling line and the spirometry tube is attached to the D-lite™ airway adapter. The D-lite™ is attached between ventilator Y-piece and Heat and moisture exchanger (HME) of the patient's intubation tube. The monitor displays measurements from the E-CAiOVX's and subtype modules in the form of numeric values, curves, and loops. All the calculated parameters can be selected on the display, and trended. Alarms for measurements provided by the E-CAiOVX modules are taken care of by the host monitor and follow the user interface for alarms in Datex-Ohmeda S/5 patient monitors, e.g. showing priorities and sources of alarms. There are auditory and visual alarms and user adjustable limits for the gas measurement variables.

#### INTENDED USE as required by 807.92(a)(5)

##### Intended use:

The Datex-Ohmeda S/5™ Compact Airway Module, E-CAiOVX family is intended to be used with Datex-Ohmeda modular multiparameter monitors for monitoring respiratory, ventilatory and gas exchange parameters of hospitalized patients.

##### Indications for use:

The Datex-Ohmeda S/5™ Compact Airway Module, E-CAiOVX family is indicated for monitoring hospital patient's respiration (CO<sub>2</sub>, O<sub>2</sub>, N<sub>2</sub>O, anesthetic agents, anesthetic agent identification and respiration rate) ventilation (airway pressure, volume and flow) and gas exchange status (Oxygen Consumption VO<sub>2</sub>, Carbon Dioxide production VCO<sub>2</sub>, Respiratory Quotient RQ, and Energy Expenditure, EE). Gas exchange status monitoring is not indicated in the presence of N<sub>2</sub>O+O<sub>2</sub> mixtures. The device is indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF DEVICE COMPARED TO THE  
PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda S/5™ Compact Airway Module family, E-CAiOVX is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M-CAiOVX Module (K001814).

The E-CAiOVX module has the following similarities compared to the predicate M-CAiOVX (K001814):

- identical intended use and indications for use
- identical fundamental scientific technology
- same electronic measurement board (EEPROM type changed)
- same module software (version changed from 891977-3.2 to 8001805-4.5)
- same algorithms for respiratory, ventilatory and gas exchange parameter calculation
- use the same operating principle
- use largely the same accessories
- have the same user interface at the monitor and alarms (can be used with the same monitor software)
- the Customer and parameter specifications are the same, except for one minor modification
- have the same safety and effectiveness
- are manufactured using the same processes

The main differences between the new E-CAiOVX and the predicate M-CAiOVX (K001814) is primarily due to fact that the new E-CAiOVX module has the following changes:

- new color and shape and thus differing mechanics
- The front panel and labeling have changed
- The connector for gas return (front panel and accessories) have changed to be incompatible with female Luer Lock connectors.
- The EEPROM type on the electronic measurement boards have changed
- The module software has been enhanced and revised several times. Most new revisions include enhancements for manufacturing and testing during manufacturing.
- The EMC is better implemented into the mechanics, e.g. some module materials changed and shielding EMC foam was used.

Based on the analysis and other documentation included in this 510(k) notification and attachments it is evident that the main features and indications for use of the Datex-Ohmeda S/5™ Compact Airway Module, E-CAiOVX are substantially equivalent to the predicate Datex-Ohmeda M-CAiOVX Module (K001814).

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Datex-Ohmeda S/5™ Compact Airway Module (model family E-CAiOVX) E-CAiOVX, E-CAiOV, E-CAiO, E-COVX, E-COV, E-CO and accessories have been assessed against the standards below. The device has been thoroughly tested through validation and verification of specifications.

- FDA/DCRND Reviewer Guidance for Premarket Notification Submissions, November 1993
- IEC 60601-1:1988 + Amdt. 1:1991 + Amdt. 2:1995 (Part 1: General requirements for safety)
- EN 60601-1:1990+ A1:1993 + A13:1996 + A2:1995 (identical to IEC60601-1:1988 + Amdt. 1:1991 + Amdt. 2:1995)
- CAN/CSA C22.2 No. 601.1-M90 + S1:1994 (Canadian deviations to IEC 60601-1:1988 + Amdt. 1:1991) + S2:1998 (=IEC Amdt 2:1995)
- UL 2601-1, October 24, 1997 (U.S. deviations to IEC 60601-1:1988 + Amdt. 1:1991+ Amdt. 2:1995)
- IEC 60601-1-2:2001 (Electromagnetic compatibility – Requirements and tests)
- IEC 60601-1-4:2000 (Programmable medical systems)
- ISO 9918 (1993) / EN 864 (1996):Capnometers for use with Humans – Requirements
- ISO 7767:1997 Oxygen monitors for monitoring breathing mixtures.
- EN 12598:1999 Oxygen monitors for monitoring breathing mixtures.
- ISO 11196:1995 + Corr. 1:1997 /EN ISO 19996 (1997) Anaesthetic gas monitors
- ASTM F-1456 (2001) Standard specification for Capnometers
- FDA/ODE Guidance for Content of Premarket Submission for Software Contained in Medical Devices. Version 1.0. (May, 29, 1998)

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda S/5™ Compact Airway Module (model family E-CAiOVX) E-CAiOVX, E-CAiOV, E-CAiO, E-COVX, E-COV, E-CO and accessories as compared to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 25 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Joel Kent  
Manager, Quality and Regulatory Affairs  
GE Healthcare  
86 Pilgrim Road  
Needham, Massachusetts 02492

Re: K051092

Trade/Device Name: Datex-Ohmeda S/5™ Compact Airway Module (model family E-CAiOVX) E-CAiOVX, E-CAiOV, E-CAiO, E-COVX, E-COV, E-CO and Accessories

Regulation Number: 21 CFR 868.1400

Regulation Name: Carbon Dioxide Gas Analyzer

Regulatory Class: II

Product Code: CCL, BZK, CAP, CBR, BZL, CBQ, CBS, NHO, NHQ, NHP

Dated: April 27, 2005

Received: April 28, 2005

Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): \_\_\_\_\_

Device Name: Datex-Ohmeda S/5™ Compact Airway Module  
(model family E-CAiOVX) E-CAiOVX, E-CAiOV, E-CAiO, E-COVX, E-  
COV, E-CO and accessories.

### Indications for Use:

The Datex-Ohmeda S/5™ Compact Airway Module, E-CAiOVX family is indicated for monitoring hospital patient's respiration (CO<sub>2</sub>, O<sub>2</sub>, N<sub>2</sub>O, anesthetic agents, anesthetic agent identification and respiration rate) ventilation (airway pressure, volume and flow) and gas exchange status (Oxygen Consumption VO<sub>2</sub>, Carbon Dioxide production VCO<sub>2</sub>, Respiratory Quotient RQ, and Energy Expenditure, EE). Gas exchange status monitoring is not indicated in the presence of N<sub>2</sub>O+O<sub>2</sub> mixtures. The device is indicated for use by qualified medical personnel only.

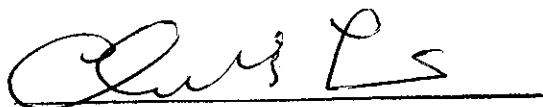
Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

Page \_\_ of \_\_

510(k) Number:   K051092